

**REMARKS/ARGUMENTS**

**35 U.S.C. §102(a) Teagarden et al. (US Publication 2002/0110561)**

Claims 1-8 and 12-13 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Teagarden et al. (US Publication 2002/0110561). In making this rejection the Examiner states that changing the amount of the modified carrier from that shown in Teagarden et al. would be "a mere matter of judicious selection and routine optimization, based upon the beneficial teachings provided by the cited reference."

In the present application, claim 1 is directed to a composition comprising one to three bioactive agents; and a vehicle comprising a modified liquid carrier and an un-modified liquid carrier wherein the ratio by volume of the modified liquid carrier to the un-modified liquid carrier is between 0.00001:99.99999 to less than 0.01:99.99, that provides the composition with predictable sustained-release properties and wherein immediately after manufacture of the composition, said composition can be administered to a host such that the one to three bioactive agents are released to the host on a sustained basis.

As the Examiner has acknowledged, the ratio by volume of the modified liquid carrier to the un-modified liquid carrier is lower in the present invention than in Teagarden et al. In discussing preferred embodiments in the Teagarden et al. state (paragraph 055), that "the ratio of modified unsaturated oil to saturated, non-oxidizing oil is from about 0.01:99.99 to about 90:10 (v/v), the total amount of each being 100 percent, with particular reference to the range from about 10:90 to about 25:75 (v/v), and most particularly from about 10:90 to about 20:80 (v/v)."

The unexpected aspect of the present invention is the low levels at which the modified oil is effective. Contrary to what would be expected by one skilled in the art of designing sustained release formulations, the Applicants have found that compositions comprising a modified liquid carrier present at concentration levels that are up to 1,000 fold lower than any concentration levels previously contemplated in the art, possessed excellent, predictable, sustained release properties.

There is no teaching in Teagarden et al. which suggests that compositions of the present invention, comprising such extremely low concentrations of modified liquid carrier in un-modified liquid carrier, would produce the desired predictable sustained release effect. The use

of extremely low levels of modified liquid carrier in an un-modified liquid carrier to provide compositions with predictable sustained release properties that are present immediately after manufacture and throughout the composition's shelf life, could not have been anticipated by a person of ordinary skill in the art based upon the teaching of Teagarden et al.

Reconsideration and withdrawal of this rejection is respectfully requested.

In view of these remarks, Applicants respectfully request reconsideration of and withdrawal of all rejections and objections. Allowance of the present application is earnestly requested.

Respectfully submitted,



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